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January 24, 2011

HAND DELIVERED

Ms. Cristy Fuqua
Wise County District Clerk
Wise County Courthouse
Decatur, Texas 76234

Re: *Christopher Helm, M.D., and Sharyn Helm, Individually and Next of Friends of Hunter Helm, a Minor, Quinn Helm, a Minor, and Rubye Helm, a Minor vs. Moog Inc.; Orthopedic Resources, Inc.; Southern Innovations, L.L.C.; Pylant Medical, Ltd.; Brett Pylant; Curlin Medical, Inc.; Stryker Corporation; Stryker Sales Corporation; Astrazeneca Pharmaceuticals LP; Astrazeneca LP; Astrazenca AB; Hospira, Inc.; Hospira Worldwide, Inc.; Abbott Laboratories; Celgene Corporation; APP Pharmaceuticals, LLC; and Eastman Kodak Company.*

Dear Ms. Fuqua,

Enclosed please find the original and one copy of the *Plaintiffs' Original Petition*. Please file original with the court and file mark said copy for return to our office.


Should you have any questions please contact our office.

Very truly yours,


Hayley Byers
Legal Assistant

4:05 **FILED** AM PM

JAN 24 2011

BRENDA ROWE
DISTRICT CLERK-WISE COUNTY, TX
BY  DEPUTY

CAUSE NUMBER (FOR CLERK USE ONLY):

COURT (FOR CLERK USE ONLY):

STYLED

Helm vs. Moog Inc. et al.

(e.g., John Smith v. All American Insurance Co; In re Mary Ann Jones; In the Matter of the Estate of George Jackson)

A civil case information sheet must be completed and submitted when an original petition or application is filed to initiate a new civil, family law, probate, or mental health case or when a post-judgment petition for modification or motion for enforcement is filed in a family law case. The information should be the best available at the time of filing. This sheet, approved by the Texas Judicial Council, is intended to collect information that will be used for statistical purposes only. It neither replaces nor supplements the filings or service of pleading or other documents as required by law or rule. The sheet does not constitute a discovery request, response, or supplementation, and it is not admissible at trial.

1. Contact information for person completing case information sheet: Name: <u>Derrick Boyd</u> Email: <u>dboyd@soplaw.com</u> Address: <u>PO Box 987</u> Telephone: <u>940-627-8308</u> City/State/Zip: <u>Decatur, Tx 76234</u> Fax: <u>940-627-8092</u> Signature: <u>[Signature]</u> State Bar No: <u>00790350</u>		Names of parties in case: Plaintiff(s)/Petitioner(s): <u>See attached</u> Defendant(s)/Respondent(s): <u>See attached</u> [Attach additional page as necessary to list all parties]		Person or entity completing sheet is: <input type="checkbox"/> Attorney for Plaintiff/Petitioner <input type="checkbox"/> Pro Se Plaintiff/Petitioner <input type="checkbox"/> Title IV-D Agency <input type="checkbox"/> Other: _____ Additional Parties in Child Support Case: Custodial Parent: _____ Non-Custodial Parent: _____ Presumed Father: _____					
2. Indicate case type, or identify the most important issue in the case (select only 1):									
Civil			Family Law						
Contract <input type="checkbox"/> Debt/Contract <input type="checkbox"/> Consumer/DTPA <input type="checkbox"/> Debt/Contract <input type="checkbox"/> Fraud/Misrepresentation <input type="checkbox"/> Other Debt/Contract: _____ Foreclosure <input type="checkbox"/> Home Equity—Expedited <input type="checkbox"/> Other Foreclosure <input type="checkbox"/> Franchise <input type="checkbox"/> Insurance <input type="checkbox"/> Landlord/Tenant <input type="checkbox"/> Non-Competition <input type="checkbox"/> Partnership <input type="checkbox"/> Other Contract: _____		Injury or Damage <input type="checkbox"/> Assault/Battery <input type="checkbox"/> Construction <input type="checkbox"/> Defamation Malpractice <input type="checkbox"/> Accounting <input type="checkbox"/> Legal <input type="checkbox"/> Medical <input type="checkbox"/> Other Professional Liability: <input type="checkbox"/> Motor Vehicle Accident <input type="checkbox"/> Premises Product Liability <input type="checkbox"/> Asbestos/Silica <input checked="" type="checkbox"/> Other Product Liability List Product: <u>rain pump</u> <input type="checkbox"/> Other Injury or Damage: _____		Real Property <input type="checkbox"/> Eminent Domain/Condemnation <input type="checkbox"/> Partition <input type="checkbox"/> Quiet Title <input type="checkbox"/> Trespass to Try Title <input type="checkbox"/> Other Property: _____ Related to Criminal Matters <input type="checkbox"/> Expunction <input type="checkbox"/> Judgment Nisi <input type="checkbox"/> Non-Disclosure <input type="checkbox"/> Seizure/Forfeiture <input type="checkbox"/> Writ of Habeas Corpus—Pre-indictment <input type="checkbox"/> Other: _____		Marriage Relationship <input type="checkbox"/> Annulment <input type="checkbox"/> Declare Marriage Void Divorce <input type="checkbox"/> With Children <input type="checkbox"/> No Children Other Family Law <input type="checkbox"/> Enforce Foreign Judgment <input type="checkbox"/> Habeas Corpus <input type="checkbox"/> Name Change <input type="checkbox"/> Protective Order <input type="checkbox"/> Removal of Disabilities of Minority <input type="checkbox"/> Other: _____		Post-judgment Actions (non-Title IV-D) <input type="checkbox"/> Enforcement <input type="checkbox"/> Modification—Custody <input type="checkbox"/> Modification—Other Title IV-D <input type="checkbox"/> Enforcement/Modification <input type="checkbox"/> Paternity <input type="checkbox"/> Reciprocity (UIFSA) <input type="checkbox"/> Support Order Parent-Child Relationship <input type="checkbox"/> Adoption/Adoption with Termination <input type="checkbox"/> Child Protection <input type="checkbox"/> Child Support <input type="checkbox"/> Custody or Visitation <input type="checkbox"/> Gestational Parenting <input type="checkbox"/> Grandparent Access <input type="checkbox"/> Parentage/Paternity <input type="checkbox"/> Termination of Parental Rights <input type="checkbox"/> Other Parent-Child: _____	
Employment <input type="checkbox"/> Discrimination <input type="checkbox"/> Retaliation <input type="checkbox"/> Termination <input type="checkbox"/> Workers' Compensation <input type="checkbox"/> Other Employment: _____		Other Civil <input type="checkbox"/> Administrative Appeal <input type="checkbox"/> Antitrust/Unfair Competition <input type="checkbox"/> Code Violations <input type="checkbox"/> Foreign Judgment <input type="checkbox"/> Intellectual Property <input type="checkbox"/> Lawyer Discipline <input type="checkbox"/> Perpetuate Testimony <input type="checkbox"/> Securities/Stock <input type="checkbox"/> Tortious Interference <input type="checkbox"/> Other: _____							
Tax <input type="checkbox"/> Tax Appraisal <input type="checkbox"/> Tax Delinquency <input type="checkbox"/> Other Tax: _____		Probate & Mental Health Probate/Wills/Intestate Administration <input type="checkbox"/> Dependent Administration <input type="checkbox"/> Independent Administration <input type="checkbox"/> Other Estate Proceedings <input type="checkbox"/> Guardianship—Adult <input type="checkbox"/> Guardianship—Minor <input type="checkbox"/> Mental Health <input type="checkbox"/> Other: _____							
3. Indicate procedure or remedy, if applicable (may select more than 1):									
<input type="checkbox"/> Appeal from Municipal or Justice Court <input type="checkbox"/> Arbitration-related <input type="checkbox"/> Attachment <input type="checkbox"/> Bill of Review <input type="checkbox"/> Certiorari <input type="checkbox"/> Class Action		<input type="checkbox"/> Declaratory Judgment <input type="checkbox"/> Garnishment <input type="checkbox"/> Interpleader <input type="checkbox"/> License <input type="checkbox"/> Mandamus <input type="checkbox"/> Post-judgment		<input type="checkbox"/> Prejudgment Remedy <input type="checkbox"/> Protective Order <input type="checkbox"/> Receiver <input type="checkbox"/> Sequestration <input type="checkbox"/> Temporary Restraining Order/Injunction <input type="checkbox"/> Turnover					

**CHRISTOPHER HELM, M.D. AND SHARYN
HELM, INDIVIDUALLY AND NEXT OF
FRIENDS OF HUNTER HELM, a Minor,
QUINN HELM, a Minor, and RUBY HELM,
a Minor**

Plaintiff,

vs.

**MOOG INC.; ORTHOPEDIC RESOURCES,
INC.; SOUTHERN INNOVATIONS, L.L.C.;
PYLANT MEDICAL, LTD.; BRETT PYLANT;
CURLIN MEDICAL, INC.; STRYKER
CORPORATION; STRYKER SALES
CORPORATION; ASTRAZENECA
PHARMACEUTICALS LP; ASTRAZENECA
LP; ASTRAZENICA AB; HOSPIRA, INC.;
HOSPIRA WORLDWIDE, INC.; ABBOTT
LABORATORIES; CELGENE
CORPORATION; APP PHARMACEUTICALS,
LLC; and EASTMAN KODAK COMPANY**

Defendants

CAUSE NO. CV11-01-063

CHRISTOPHER HELM, M.D., AND SHARYN §
HELM, INDIVIDUALLY AND NEXT OF §
FRIENDS OF HUNTER HELM, a Minor, §
QUINN HELM, a Minor, and RUBY HELM, §
a Minor §

Plaintiff,

vs.

MOOG INC.; ORTHOPEDIC RESOURCES, §
INC.; SOUTHERN INNOVATIONS, L.L.C.; §
PYLANT MEDICAL, LTD.; BRETT PYLANT; §
CURLIN MEDICAL, INC.; STRYKER §
CORPORATION; STRYKER SALES §
CORPORATION; ASTRAZENECA §
PHARMACEUTICALS LP; ASTRAZENECA §
LP; ASTRAZENICA AB; HOSPIRA, INC.; §
HOSPIRA WORLDWIDE, INC.; ABBOTT §
LABORATORIES; CELGENE §
CORPORATION; APP PHARMACEUTICALS, §
LLC; and EASTMAN KODAK COMPANY §

Defendants

IN THE DISTRICT COURT

WISE COUNTY, TEXAS

271ST JUDICIAL DISTRICT

PLAINTIFFS' ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

Comes now Christopher Helm, M.D., and Sharyn Helm, individually and as Next of Friends of Hunter Helm, a minor, Quinn Helm, a minor, and Rubye Helm, a minor (hereinafter "Plaintiffs"), and files this Original Petition against Moog Inc.; Orthopedic Resources, Inc.; Southern Innovations, L.L.C.; Pylant Medical, Ltd.; Brett Pylant; Curlin Medical, Inc.; Stryker Corporation; Stryker Sales Corporation; AstraZeneca Pharmaceuticals LP; AstraZeneca LP; AstraZenica AB; Hospira, Inc.; Hospira Worldwide, Inc.; Abbott Laboratories; Celgene Corporation; APP Pharmaceuticals, LLC; and Eastman Kodak Company (hereinafter "Defendants"), and for cause of action would respectfully show as follows: 4:05 AM PM

JAN 24 2011

1.0 Discovery Plan

1.1 Pursuant to TRCP 190.1 Plaintiffs respectfully request that discovery in this case be conducted under Level 3 by further order of this Court, as set forth in TRCP 190.4.

2.0 Parties

2.1 Plaintiff is an individual and resident of Decatur, Wise County, Texas.

2.2 Defendant Moog Inc. is a foreign corporation incorporated under the laws of the State of New York with the corporate headquarters is located at 300 Jamison Road, East Aurora, New York 14052, and may be served with process by serving the Texas Secretary of State, 1019 Brazos Street, Austin, Texas 78701, as its agent for service because Defendant has not designated or maintained a resident agent for service of process in Texas, as required by statute.

2.3 Defendant Orthopedic Resources, Inc. is an Oklahoma corporation with its corporate headquarters located at 1638 South Main, Tulsa, Oklahoma 74119, and may be served with process doing business in Texas and may be served with process by serving the Texas Secretary of State, 1019 Brazos Street, Austin, Texas 78701, as its agent for service because Defendant has not designated or maintained a resident agent for service of process in Texas, as required by statute.

2.4 Defendant Southern Innovations, L.L.C., is a Texas limited liability company duly authorized to do business in Texas with its principal place of business located in Texas, and may be served with process through its registered agent for service of process: Brett Pylant, 1612 Fair Oaks, Westlake, Texas 76262.

2.5 Defendant Pylant Medical, Ltd. is a Texas corporation duly authorized to do business with its principal place of business located in Texas, and may be served with process

through its registered agent for service of process: Brett Pylant, 1612 Fair Oaks, Westlake, Texas 76262.

2.6 Defendant Brett Pylant is an individual who may be served with process at his place of residence at 1612 Fair Oaks, Westlake, Texas.

2.7 Defendant AstraZeneca Pharmaceuticals LP is a foreign limited partnership duly authorized to do business in Texas and may be served through its registered agent for service: CT Corporation System, 350 North St. Paul Street, Dallas, Texas 75201.

2.8 Defendant AstraZeneca LP is a foreign limited partnership duly authorized to do business in Texas and may be served through its registered agent for service: CT Corporation System, 350 North St. Paul Street, Dallas, Texas 75201.

2.9 Defendant AstraZenica AB is a foreign corporation duly authorized to do business in Texas and may be served through its registered agent for service: CT Corporation System, 350 North St. Paul Street, Suite 2900, Dallas, Texas 75201.

2.10 Defendant Hospira, Inc. is a foreign corporation duly authorized to do business in Texas and may be served through its registered agent for service: C T Corporation System, 350 North St. Paul Street, Suite 2900, Dallas, Texas 75201.

2.11 Defendant Hospira Worldwide, Inc. is a foreign corporation duly authorized to do business in Texas and may be served through its registered agent for service: C T Corporation System, 350 N. St. Paul Street, Suite 2900, Dallas, Texas 75201.

2.12 Defendant Abbott Laboratories is a foreign corporation duly authorized to do business in Texas and may be served through its registered agent for service: CT Corp System, 350 N. St. Paul Street, Suite 2900, Dallas, Texas 75201.

2.13 Defendant Celgene Corporation is a foreign corporation incorporated under the laws of the State of New Jersey with the corporate headquarters located at 86 Morris Avenue, Summit, New Jersey 07901, and may be served with process by serving the Texas Secretary of State, 1019 Brazos Street, Austin, Texas 78701, as its agent for service because Defendant has not designated or maintained a resident agent for service of process in Texas, as required by statute.

2.14 Defendant APP Pharmaceuticals, L.L.C., is a foreign limited liability company duly authorized to do business in Texas and may be served through its registered agent for service: Corporation Service Company dba CSC – Lawyers Incorporating Service Company, 211 E. 7th Street, Suite 620, Austin, Texas 78701-3218.

2.15 Defendant Eastman Kodak Company is a foreign corporation duly authorized to do business in Texas and may be served through its registered agent for service: CT Corp System, 350 N. St. Paul Street, Suite 2900, Dallas, Texas 75201.

2.16 Defendant Curlin Medical, Inc. is a foreign corporation incorporated under the laws of the State of California with the corporate headquarters located at 15751 Graham Street, Huntington Beach, California 72649 and may be served with process by serving the Texas Secretary of State, 1019 Brazos Street, Austin, Texas 78701, as its agent for service because Defendant has not designated or maintained a resident agent for service of process in Texas, as required by statute. Curlin was acquired by Defendant Moog in April 2006.

2.17 Defendant Stryker Corporation is a foreign corporation incorporated under the laws of the State of Michigan with the corporate headquarters located at 2825 Airview Blvd., Kalamazoo, MI 49002 and may be served with process by serving the Texas Secretary of State,

1019 Brazos Street, Austin, Texas 78701, as its agent for service because Defendant has not designated or maintained a resident agent for service of process in Texas, as required by statute.

2.18 Defendant Stryker Sales Corporation is a foreign corporation incorporated under the laws of the State of Michigan with the corporate headquarters located at 2825 Airview Blvd., Kalamazoo, MI 49002 and may be served with process by serving the Texas Secretary of State, 1019 Brazos Street, Austin, Texas 78701, as its agent for service because Defendant has not designated or maintained a resident agent for service of process in Texas, as required by statute.

3.0 Jurisdiction and Venue

3.1 This case arises out of the insertion of a pain pump into the shoulder of Plaintiff in Decatur, Wise County, Texas.

3.2 This Court has jurisdiction over this matter for the reason that the amount in controversy exceeds the jurisdictional minimum of this court, exclusive of costs and interest, and for the reason that one or more defendants are residents of the State of Texas.

3.3 Venue is proper in Wise County under Texas Civil Practice and Remedies Code §15.002(a)(1) because all or a substantial part of the event or omissions giving rise to this cause of action occurred in Wise County.

4.0 Factual Background

4.1 On or about February 13, 2008, Plaintiff Christian Helm, M.D., (hereinafter "Dr. Helm") underwent surgery on his left shoulder to repair a left shoulder labral tear at Wise Regional Health System in Wise County, Texas. At the conclusion of the surgery, Dr. Helm's surgeon implanted a pain pump catheter into Dr. Helm's left shoulder to administer post-operative pain relief medication, marcaine, on a continuous basis.

4.2 The Accufuser pain pump in question (hereinafter “Accufuser pain pump”) was originally designed, manufactured, marketed and placed into the stream of commerce by Defendant Moog Inc. Defendants Orthopedic Resources, Inc., Southern Innovations, L.L.C.; Pylant Medical, Ltd., and Brett Pylant distributed and marketed the Accufuser pain pump. Defendant Brett Pylant was the representative who sold the Accufuser pain pump to Wise Regional Health Systems.

4.3 The anesthetic drug used in the Accufuser pain pump was marcaine. This drug was manufactured, distributed and marketed by Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP; AstroZeneca AB; Hospira, Inc.; Hospira Worldwide, Inc.; Abbott Laboratories; Celgene Corporation; APP Pharmaceuticals LLC; and Eastman Kodak Company (hereinafter “Anesthetic Defendants”).

4.4 The continuous injection of drugs directly into the shoulder joint causes serious and permanent damage to the cartilage of the shoulder joint. Dr. Helm had an Accufuser pain pump inserted into his left shoulder during the surgery and received doses of continuously injected anesthetics in his shoulder joint post-operation.

4.5 As a result of the insertion of the Accufuser pain pump and continuous injection of anesthetics for a period of time, by and through the Accufuser pain pump, Dr. Helm suffered serious and permanent damages to his shoulder joint, which caused an irreversible, disabling and extremely painful condition of chondrolysis. Chondrolysis is the complete or nearly complete loss of cartilage in the shoulder joint leaving bone on bone.

4.6 Defendants Moog Inc.; Curlin Medical, Inc.; Stryker Corporation; Stryker Sales Corporation; Orthopedic Resources, Inc.; Southern Innovations, L.L.C.; Pylant Medical, Ltd; and Brett Pylant (hereinafter “Pain Pump Defendants”) manufactured, distributed and/or marketed

pain pumps without doing a single study (or, alternatively, sufficient study) to determine the safety of high-volume pain pumps, or what damage could be caused when physicians placed the catheter into the shoulder, much less directly into the shoulder joint space. The Anesthetic Defendants, similarly, did nothing to investigate whether the continuous and high-volume infusion of their drugs into and near shoulder joint spaces was harmful. Instead, Defendants encouraged orthopedic surgeons to use the pumps and anesthetics, in tandem, in an untested and dangerous manner.

4.7 Manufacturers such as Defendants Moog Inc., Curlin Medical, Inc.; Stryker Corporation; and Stryker Sales Corporation sought approval from the Food and Drug Administration (FDA) for the placement of the catheter in the shoulder joint space beginning in the late 1990s. For lack of safety information, the FDA rejected their application multiple times. Nevertheless, Defendants chose not to advise physicians about these dangers, not to advise patients of these risks, and not to tell physicians that their FDA applications were rejected. Instead, the Pain Pump Defendants continued to sell and market these pumps with reckless indifference – all to the detriment of thousands of patients generally, and to Dr. Helm in particular.

4.8 The Pain Pump Defendants never provided any warning or disclosed any information that the Accufuser pain pump used in Dr. Helm's surgery was not suitable for the intended purpose of use after shoulder surgeries to administer post-operative pain relief medication, marcadine, on a continuous basis. More specifically, the Pain Pump Defendants never provided any warning that use of the Accufuser pain pump could cause chondrolysis or that its use as a pain pump for shoulder surgery had been specifically rejected by the FDA.

4.9 The Anesthetic Defendants also chose not to advise physicians or patients about the dangers of pain pump anesthetics. Specifically, the Anesthetic Defendants never provided any warning or disclosed any information that the marcaine injected into Dr. Helm's shoulder through the Accufuser pain pump was not suitable for the intended purpose of use in a pain pump after shoulder surgery. More specifically, the Anesthetic Defendants never provided any warning that use of the Accufuser pain pump could cause chondrolysis or that its use as a pain pump for shoulder surgery had been specifically rejected by the FDA.

4.10 Instead, Defendants continued to sell and market these pain pumps and pain pump anesthetics with reckless indifference – all to the detriment of thousands of patients generally, and Dr. Helm in particular. In a report titled “Information for Healthcare Professions – Chondrolysis Reported with Continuously Infused Local Anesthetics (marketed and bupivacaine, chlorprocaine, lidocaine, mpeivacaine, procaine and ropivacaine) dated November 13, 2009 and updated on February 16, 2010, the FDA specifically stated that

[b]ased on the reported cases of chondrolysis following continuous intra-articular infusion of local anesthetics with elastomeric infusion devices, the FDA is requiring the manufacturers of local anesthetics and of pumps that may be used to infuse local anesthetics to update their product labels to warn healthcare professions about this potential serious adverse effect. FDA is also exploring possible options for addressing the safety issues with the infusion devices (e.g., labeling changes, etc.). Because the reported cases involved significant injury to otherwise health young adults, FDA wants to advise healthcare professionals that elastomeric infusion devices or any other infusion pump are not cleared by FDA to deliver intra-articular infusions of local anesthetics and should not be used for this purpose.

4.11 Despite the exercise of reasonable care and diligence, Plaintiffs did not discover and could not discover the existence of their claims until within two years of the date of commencing this action.

5.0 Conditions Precedent

5.1 All conditions precedent have been performed or have occurred. TEX.R.CIV.P. 54.

6.0 Causes of Action

6.1 *Negligence*: Defendants had a duty to exercise ordinary care in the design, manufacture, testing, marketing and distribution of the Accufuser pain pump and the anesthetic marcaine to ensure that they were not unreasonably dangerous for their foreseeable use in shoulder surgeries to continuously inject anesthetic into the shoulder joint space. Defendants knew, or in the exercise of ordinary care should have known, that the Accufuser pain pump and anesthetic marcaine was defective and/or unreasonably dangerous to those persons undergoing shoulder surgery in which a pain pump is inserted into the shoulder joint space and anesthetics are continuously injected into the shoulder space. Defendants breached their duty of care by:

- (a) Failing to instruct and/or warn that the safety of the pain pump with continuously injected anesthetic had not been established for use in the shoulder joint space;
- (b) Failing to instruct and/or warn that continuous injection of commonly used anesthetics such as marcaine may cause serious and permanent injury to the joint cartilage;
- (c) Failing to warn against placing the catheter of the pain pump in the joint space;
- (d) Failing to warn and instruct regarding the safe use of the devices with continuously injected anesthetics, including instructions regarding the appropriate location and placement of the catheter within the shoulder joint space;
- (e) Failing to warn that the effectiveness of the pump was uncertain for use in the shoulder joint space;
- (f) Failing to instruct and/or warn that use of the pain pump with continuously injected anesthetic in the shoulder joint had not been approved by the FDA; and
- (g) Failing to instruct and/or warn that the applications for such use had been rejected by the FDA.

Defendants' negligence was a proximate cause of Plaintiffs' injuries and damages more fully set forth below.

6.2 ***Strict Liability – Design Defect:*** The Pain Pump Defendants and Anesthetic Defendants are responsible for Plaintiffs' damages because there was a design defect in the Accufuser pain pump and marcaine at the time the Accufuser pain pump and marcaine left their possession that was the producing cause of Plaintiffs' damages. Specifically, (a) the Accufuser pain pump and marcaine were unreasonably dangerous and defective as designed, taking into consideration the utility of the subject Accufuser pain pump and marcaine and risks involved in their use; (b) there were safer alternative designs other than the design utilized by Defendants in the Accufuser pain pump and marcaine that would have prevented or significantly reduced Dr. Helm's injuries; and (c) these alternative designs were both economically and technologically feasible by the application of existing or reasonably achievable scientific knowledge at the time the Accufuser pain pump and marcaine left control of Defendants. This design defect was a producing cause of Plaintiffs' damages more fully set forth below.

6.3 ***Strict Liability - Manufacturing Defects:*** Pain Pump Defendants and Anesthetic Defendants are responsible for the injuries sustained by Plaintiffs because there was a manufacturing defect in the Accufuser pain pump and marcaine used in Dr. Helm's shoulder surgery that was the producing cause of Plaintiffs damages. Specifically, the Accufuser pain pump manufactured by the Pain Pump Defendants and the pain pump anesthetic manufactured by the Anesthetic Defendants deviated in its construction or quality from the specifications or planned output in a manner that rendered them unreasonably dangerous. The Pain Pump Defendants and Anesthetic Defendants are entities engaged in the business of selling the Accufuser pain pump and marcaine such as those in question, and actually placed the Accufuser

pain pump and marcaine in question into the stream of commerce containing the defect. As such, the Pain Pump Defendants and Aesthetic Defendants are liable for the manufacturing defect that was a producing cause of Plaintiffs' damages more fully set forth below.

6.4 ***Strict Liability – Marketing Defect:*** Pain Pump Defendants and Aesthetic Defendants are responsible for the Plaintiffs' damages because there were marketing defects in the Accufuser pain pump and marcaine used in Dr. Helm's surgery at the time the Accufuser pain pump and marcaine left the possession of Pain Pump Defendants and Aesthetic Defendants that was the producing cause of Plaintiffs' damages. Specifically, the Pain Pump Defendants and Aesthetic Defendants failed to give adequate warnings about the products' dangers including but not limited to the following:

- (a) the labeling and instructions failed to warn that the safety of the pain pump with continuously injected anesthetic had not been established for use in the shoulder joint;
- (b) the labeling and instructions failed to warn that continuous injection of commonly used anesthetics such as marcaine may cause serious and permanent injury to the joint cartilage;
- (c) the labeling and instruction failed to warn against placing pain pump catheters into the joint shoulder space;
- (d) the product did not contain adequate instructions for safe use of medications and proper location of catheters;
- (e) the labeling and instructions failed to warn that the effectiveness of the product for use within the shoulder joint was undetermined;
- (f) Failing to instruct and/or warn that use of the pain pump with continuously injected anesthetic in the shoulder joint had not been approved by the FDA; and
- (g) Failing to instruct and/or warn that the applications for such use had been rejected by the FDA.

These dangers were known or by the application of reasonably developed skill and foresight by those in the industry should have been known. As such, the Pain Pump Defendants and

Aesthetic Defendants are liable for the marketing defect that was a producing cause of Plaintiffs' injuries and therefore strictly liable for the damages sustained by Plaintiffs more fully set forth below.

6.5 ***Implied Warranty of Merchantability:*** The Texas Uniform Commercial Code provides for an implied warranty of merchantability on products sold in Texas. [Texas Business & Commerce Code §2.314(b)] There were no written disclaimers or modifications of any implied warranty at the time of sale. As such, there was an implied warranty that the Accufuser pain pump and anesthetic marcaine in question were merchantable. Defendants breached this implied warranty because the Accufuser pain pump and anesthetic marcaine in question were of such condition as to render them unfit for the ordinary purpose for which they were to be used. This breach of the implied warranty of merchantability by Defendants was a proximate cause of Plaintiffs' injuries and damages more fully set forth below.

6.6 ***Implied Warranty of Fitness for a Particular Purpose:*** The Texas Uniform Commercial Code provides for an implied warranty of fitness for a particular purpose on products sold in Texas. [Texas Business & Commerce Code §2.315] There were no written disclaimers or modifications of any implied warranty at the time of sale. As such, there was an implied warranty that the Accufuser pain pump and anesthetic marcaine in question were fit for the particular purpose of use after shoulder surgeries to administer the post-operative pain relief medication marcaine on a continuous basis. Defendants had reason to know the particular purpose for which the Accufuser pain pump and anesthetic marcaine was intended, and users like Dr. Helm would rely on the skill and judgment of Defendants to furnish a suitable Accufuser pain pump and anesthetic marcaine. Defendants breached this implied warranty because the pain pump Accufuser and pain pump anesthetic marcaine in question were not suitable for use in the

shoulder of Dr. Helm. This breach of the implied warranty of fitness for a particular purpose by Defendants was a proximate cause of Plaintiffs' injuries and damages more fully set forth below.

6.7 Breach of Express Warranty: Defendants Pylant Medical, Ltd.; Southern Innovations, L.L.C. and Brett Pylant made an express warranty that the Accufuser pain pump in question was a "safe" and "good" product suitable for use after shoulder surgery to administer post-operative pain relief medication. However, the Accufuser pain pump did not live up to the express warranty given by Defendants Pylant Medical, Ltd.; Southern Innovations, L.L.C. and Brett Pylant. This breach of express warranty was a proximate and/or producing cause of Plaintiffs' damages more fully set forth below.

6.8 Liability under §82.003(a) of the Texas Civil Practice and Remedies Code: Plaintiffs specifically alleges that Defendants Orthopedic Resources, Inc.; Pylant Medical, Ltd.; Southern Innovations, L.L.C. and Brett Pylant are not "innocent sellers" as that term is used in Texas law and, more specifically, are liable because their conduct fits within one or more of the exceptions contained in Texas Civil Practice & Remedies Code §82.003(a). Based on the foregoing, Plaintiffs specifically allege that Defendants Orthopedic Resources, Inc.; Pylant Medical, Ltd.; Southern Innovations, L.L.C. and Brett Pylant are liable to Dr. Helm for the following reasons:

- (1) they "exercised substantial control over the content of a warning or instruction that accompanied the product [that was] inadequate and the claimant's harm resulted from the inadequacy of the warning or instruction" by representing that the pain pump Accufuser was suitable for use after shoulder surgery to administer post-operative pain relief medication; [Texas Civil Practice & Remedies Code §82.003(a)(4)];
- (2) they "made an express factual representation about an aspect of the product [i.e. that it was suitable for its intended use] [that was] incorrect" and relied upon by Dr. Helm and Dr. Helm's surgeon resulting in Dr. Helm's damages and if the aspect of the produce had been as represented Dr. Helm would not have been harmed by the product [Texas Civil Practice & Remedies Code §82.003(a)(5)]; and

- (3) they “actually knew of a defect to the [pain pump Accufuser] at the time the seller supplied the” it to Dr. Helm “and the claimant’s harm resulted from the defect” [Texas Civil Practice & Remedies Code §82.003(a)(6).

Such conduct constitutes negligence or strict liability and was a proximate and/or producing cause of Plaintiffs’ damages more fully set forth below.

7.0 Causation

7.1 As a result of the acts and omissions of the Defendants, Plaintiff Christopher Helm, M.D., suffered severe, permanent and disabling injuries during the occurrence in question.

7.2 These acts and omissions were a proximate, producing and cause-in-fact of Plaintiffs’ damages more fully set forth below.

8.0 Damages

8.1 *Christopher Helm, M.D.:* As a result of these injuries, Dr. Helm is entitled to recover compensatory damages in an amount that exceeds the jurisdictional minimum of this court for each of the following elements:

- a. expenses for medical care paid or incurred in the past; and medical care that, in reasonable probability, Plaintiff will incur in the future;
- b. lost earnings and earning capacity in the past; and loss of earning capacity that, in reasonable probability, Plaintiff will sustain in the future;
- c. physical impairment sustained in the past; and physical impairment that, in reasonable probability, Plaintiff will sustain in the future;
- d. disfigurement sustained in the past; and disfigurement that, in reasonable probability, Plaintiff will sustain in the future;
- e. physical pain sustained in the past; and physical pain that, in reasonable probability, Plaintiff will sustain in the future; and
- f. mental anguish sustained in the past; and mental anguish that, in reasonable probability, Plaintiff will sustain in the future.

8.2 ***Sharyn Helm (for the injury of her husband):*** Plaintiff Sharyn Helm, as the wife of Christopher Helm, M.D., is entitled to recover damages sustained in the past and that in all reasonable probability will be sustained in the future as a result of the severe, permanent and disabling injury sustained by her husband, Christopher Helm, M.D. during the occurrence in question in an amount that exceeds the jurisdictional limits of this Court for each of the following elements:

- a. loss of household services sustained in the past; and loss of household services, in reasonable probability, Sharyn Helm will sustain in the future; and
- b. loss of consortium sustained in the past; and loss of consortium, in reasonable probability, Sharyn Helm will sustain in the future.

8.3 ***Hunter Helm (for injury of his father):*** Plaintiff Hunter Helm, as the son of Christopher Helm, M.D., is entitled to recover damages sustained in the past and that in all reasonable probability will be sustained in the future as a result of the severe, permanent and disabling injury sustained by his father, Christopher Helm, M.D., during the occurrence in question in an amount that exceeds the jurisdictional limits of this Court for the following elements: loss of parental consortium sustained in the past; and loss of parental consortium, in reasonable probability, Hunter Helm will sustain in the future.

8.4 ***Quinn Helm (for injury of her father):*** Plaintiff Quinn Helm, as the daughter of Christopher Helm, M.D., is entitled to recover damages sustained in the past and that in all reasonable probability will be sustained in the future as a result of the severe, permanent and disabling injury sustained by her father, Christopher Helm, M.D., during the occurrence in question in an amount that exceeds the jurisdictional limits of this Court for the following elements: loss of parental consortium sustained in the past; and loss of parental consortium, in reasonable probability, Quinn Helm will sustain in the future.

8.5 ***Ruby Helm (for injury of her father):*** Plaintiff Ruby Helm, as the daughter of Christopher Helm, M.D., is entitled to recover damages sustained in the past and that in all reasonable probability will be sustained in the future as a result of the severe, permanent and disabling injury sustained by her father, Christopher Helm, M.D., during the occurrence in question in an amount that exceeds the jurisdictional limits of this Court for the following elements: loss of parental consortium sustained in the past; and loss of parental consortium, in reasonable probability, Ruby Helm will sustain in the future.

9.0 Exemplary Damages

9.1 The conduct of Defendants was more than momentary thoughtlessness, inadvertence, or error of judgment, and was of such a character as to make the Defendants guilty of gross neglect. Defendants' actions involve such an entire want of care as could have resulted only from a conscious indifference to the rights, safety or welfare of Dr. Helm.

9.2 Exemplary damages in an amount to be determined by the trier of fact for the purpose of deterring similar conduct in the future and for all purposes authorized and permitted under Texas law.

10.0 Demand for Jury

10.1 Plaintiffs demand their right to a jury trial afforded by the Texas Constitution and the United States Constitution and have previously tendered the requisite fee to the district clerk.

11.0 Request for Disclosure

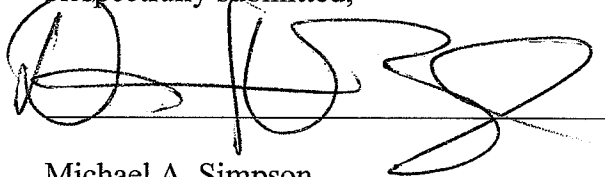
11.1 Pursuant to Texas Rule of Civil Procedure 194, Defendant is requested to disclose all information as provided by Rule 194.2 within fifty (50) days of being served with a copy of this request and this Original Petition.

PRAYER

WHEREFORE, Plaintiffs requests that Defendants be cited to appear and answer, and that on final trial Plaintiffs, have:

- a. Judgment against Defendants, jointly and severally, for an amount in excess of the minimum jurisdictional limits of the Court for compensatory damages more fully set forth above;
- b. Judgment against Defendants, jointly and severally, for an amount in excess of the minimum jurisdictional limits of the Court for exemplary damages more fully set forth above;
- c. Prejudgment and post-judgment interest as provided by law;
- d. Costs of suit; and
- e. Such other and further relief to which Plaintiffs may be justly entitled.

Respectfully submitted,

A handwritten signature in black ink, appearing to be "Michael A. Simpson", written over a horizontal line.

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